K062086

SEP 20 2006

510 (k) Summary of Safety and Effectiveness for NaviVision

Manufacturer:

Address: BrainLAB AG
Kapellenstraße 12
85622 Feldkirchen
Germany
Phone: +49 89 99 15 68 0
Fax: +49 89 99 15 68 33

Contact Person: Mr. Rainer Birkenbach

Summary Date: July 06, 2006

Device Name:

Trade name: NaviVision

Common/Classification Name: NaviVision, BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Device:

BrainLAB VectorVision fluoro ^{3D} (K024192)
BrainLAB Kolibri spine (K042721)

Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II

Intended Use:

Indications For Use:
BrainLAB's NaviVision is an add-on system for the Siemens mobile x-ray system Siemens Arcadis Orbic, including the 3D option Arcadis Orbic3D, and the Siemens mobile x-ray system Siemens Arcadis Varic. The NaviVision system is intended as an intraoperative image-guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or intraoperative image data.
The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, for which imaging using the Siemens mobile x-ray system has been cleared, and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image and/or image data-based model of the anatomy.

Device Description:

NaviVision is a device that allows surgical planning and navigation on datasets acquired with digital Siemens C-arms. No extra navigation platform is required in the surgical theatre, since the BrainLAB navigation computer is built in the Siemens C-arm trolley.
NaviVision links a surgical instrument, (tracked by passive marker sensor system) to a location on a virtual computer image, which is either based on an intraoperative patient's 3D scan or on patient's intraoperatively acquired 2D fluoro image with a digital Siemens C-arm.

The device enables the navigation based on 3D scan data and / or based on acquired fluoro images.

Based on 2D fluoro images, the registration is done automatically by using the exact spatial position information of the intra-operatively acquired fluoro images.

Based on 3D data, the registration is also done automatically by using the exact spatial position information of the start position of the scan. Beforehand, the 3D Siemens C-arm has to be calibrated in combination with the navigation system.

For 3D data, the paired point matching is also available as a re-registration method. Re-registration is a method to regain the navigation accuracy in case of a movement of the patient's reference. By using this option, another 3D scan is not necessary.

The C- Arm and its components are manufactured by Siemens AG Medical Solutions.
BrainLAB AG manufactures the integrated NaviVision Platform and its components.
The components of the NaviVision platform and the C- Arm are delivered by Siemens.
On site installation and customer training is performed by a qualified BrainLAB support engineer.

Substantial equivalence:
NaviVision has been verified and validated according to BrainLAB's procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate device BrainLAB VectorVision fluoro ^{3D} (K024192) and BrainLAB Kolibri spine (K042721).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 2006

BrainLAB AG
% Mr. Rainer Birkenbach
Executive Vice President
Kappellenstraße 12
85622 Feldkirchen Germany

Re: K062086
Trade/Device Name: NaviVision
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: July 17, 2006
Received: July 21, 2006

Dear Mr. Birkenbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062086

Device Name: NaviVision

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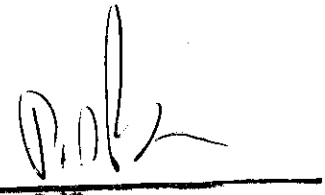
Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062086